DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

9/7/11d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 596-7700

August 30, 2001

WARNING LETTER

NWE-37-01W

FEDERAL EXPRESS

John Lees, President and Owner
Mar-Lees Seafood, Inc.
110 Herman Melville Boulevard
New Bedford, Massachusetts 02740

Dear Mr. Lees:

We inspected your firm, located at 110 Herman Melville Boulevard in New Bedford, MA, on May 9 and 10, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR 123). These deviations cause the raw, individually quick frozen (IQF) shrimp being processed (repackaged) by your firm to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations though links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR §123.6(c)(3). Your firm's HACCP plan for IQF peeled and deveined shrimp (CCP-frozen received ocean caught) lists a critical limit, [redacted], that is not adequate to control the sulfite hazard in your shrimp. The hazard of undeclared sulfites exists at levels below [redacted].

The raw material receiving step does not need to be identified as a CCP for control of the presence of sulfites in shrimp, provided that, the finished product labeling step is

identified as a CCP and there are proper monitoring and control procedures to assure that sulfite containing shrimp processed by your firm is properly labeled.

Your firm's HACCP plan for IQF peeled and deveined shrimp at the labeling critical control point fails to include in the "WHAT" column:

- labeling or accompanying documents for each lot received from another processor for the presence of sulfiting agent declaration; or
- a suppliers lot-by-lot certificate that no sulfiting agent was used; or
- a representative sample of each lot for sulfiting agent is tested for sulfite residues.

Testing and certification at the raw material receiving step will be necessary to ensure control at the finished product labeling CCP.

Further the HACCP plan at the labeling CCP should identify "sulfiting agents" as the "Hazard" and the critical limit should be "Finished product labels for product processed from sulfite containing raw material must contain a sulfite agent declaration."

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

In addition, your firm routinely produces ready-to-eat seafood, such as cooked shrimp. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR §123.11(b). However, your firm has failed to maintain sanitation control records documenting the monitoring of the following:

1. Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
2. Protection of food, food packaging materials, and food contact surfaces from adulteration with contaminants;
3. Proper labeling, storage, and use of toxic compounds; and
4. Exclusion of pests from the food plant.

Conditions and practices requiring sanitation monitoring are set forth in 21 CFR §123.11(b). Sanitation control records are required under 21 CFR §123.11(c).

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as a completed HACCP plan and sanitation monitoring records, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR §110).

You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Lookabaugh at (781) 596-7751.

Sincerely,

Gail T. Costello
District Director
New England District